

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

THOMAS A. SIMONIAN,

Relator,

v.

ASTELLAS PHARMA US, INC.,

Defendant.

Civil Action No. 1:10-cv-01539

Honorable Sharon Johnson Coleman

JURY TRIAL DEMANDED

JOINT STATUS REPORT

In accordance with the Court's September 9, 2010 Minute Entry (Dkt. #41) the undersigned parties submit the following Joint Status Report.

1. The Nature of the Case

a) The Attorneys of Record

Counsel for the Relator Thomas A. Simonian ("Simonian") are Joseph M. Vanek and John P. Bjork of Vanek, Vickers & Masini, P.C. Mr. Vanek will serve as lead trial attorney for Simonian. Additional counsel for Simonian are Bruce S. Sperling and Robert D. Cheifetz of Sperling & Slater, P.C., as well as Martin Goering and Jessica E. Rissman of Eugene M. Cummings, P.C.

Counsel for Defendant Astellas Pharma US, Inc. ("Astellas") are Gregory S. Norrod and Jaclyne D. Wallace of Foley & Lardner, LLP. Mr. Norrod will serve as the lead trial attorney for Astellas.

b) The Nature of the Claims Asserted

Simonian's complaint (Dkt. #1), filed on March 9, 2010, is a *qui tam* action on behalf of the United States of America for false patent marking under 35 U.S.C. § 292. Specifically, Simonian has alleged that Astellas has violated 35 U.S.C. § 292(a) by affixing the packaging and

the package insert of its AMEVIVE® product (an immune system suppressing prescription drug for the treatment of psoriasis, a chronic skin disorder) with US Pat. No. 4,956,281 (“the ‘281 Patent”) which expired no later than September 11, 2007). Simonian further alleges that Astellas knew or should have known that the ‘281 Patent had expired and that Astellas continued to mark its products with the intent to deceive the public as to the correct status of its Intellectual Properties.

Because Astellas has moved to dismiss, it has not been required to answer or assert any counterclaims. Astellas contends that it did not have knowledge of the expiration of the ‘281 Patent and that it did not continue marking with any intent to deceive.

c) The Principal Legal and Factual Issues in this Case

The principal legal issue in this case is whether Astellas has falsely marked certain of its products with the intent to deceive the public in violation of 35 U.S.C. § 292. *See Pequignot v. Solo Cup Company*, 608 F.3d at 1362-63.

The principal factual issues in this case are: (1) whether Astellas marked and continues to mark certain of its products with the expired ‘281 Patent; (2) whether Astellas knew that the ‘281 Patent had expired; (3) whether Astellas had an intent to deceive the public; (4) the number of products Astellas manufactured that were marked with the ‘281 Patent after its expiration; (5) the number of instances Astellas has used the expired ‘281 Patent in advertising in connection with any of its products; and (6) the appropriate amount of a civil monetary fine under 35 U.S.C. § 292 not to exceed \$500 per false marking “offense” (one half of which must be paid to the United States of America).

d) The Relief Sought by Simonian

Pursuant to 35 U.S.C. § 292, Simonian seeks the imposition of a civil monetary fine of up to \$500 per false marking “offense,” or an alternative amount as determined by the Court, one half of which shall be paid to the United States of America.

e) The General Status of the Case

This case was initiated on March 9, 2010 with the filing of Simonian’s complaint (Dkt. #1). On May 10, 2010, Astellas filed a Motion to Dismiss Pursuant to Rule 9(b) and 12(b)(6) (Dkt. #16 and #17).¹ Simonian filed his Response in Opposition to Astellas’s Motion on June 11, 2010 (Dkt. #23). Astellas filed its Reply on June 25, 2010 (Dkt. #25). Subsequently, the parties each submitted a number of supplemental authorities to keep the Court informed of recent developments. To date, the Court has not ruled on Astellas’s Motions.

2. Pending Motions

As addressed above, a Motion to Dismiss Pursuant to Rule 9(b) and 12(b)(6) (Dkt. #16 and #17) is currently pending.

3. Remaining Discovery

a) The general type of discovery remaining

The parties are awaiting a ruling on the pending Motions and discovery has not begun. Discovery is anticipated on the following topics: (1) the total unit number of marked products produced or distributed by Astellas accused in Simonian’s Complaint after expiration of the ‘281 Patent; (2) financial information regarding the sale of the falsely marked product(s); (3) Astellas’s process for determining whether and what patent numbers to affix to products; (4) Astellas’s policies related to patent marking; (5) Astellas’s knowledge and intent with respect to

¹ Astellas also filed motions to dismiss based on standing and to stay pending the Federal Circuit’s decision of a case involving standing issues in false marking cases. Those motions have been withdrawn (*See* Dkt. Nos. 35 & 36.).

marking the '281 Patent on its marked product(s) after expiration of that patent; and (6) Simonian's investigation and knowledge regarding Astellas's marking.

A proposed protective order will be submitted to the court for approval by on or before the open of discovery; pending the entry of a protective order specific to this case, the parties will operate under the Protective Order that applies to patent cases under the Local Patent Rules. *See Appendix B Local Patent Rules.*

Simonian expects he will need approximately five (5) depositions; Astellas expects to take no more than two (2) fact depositions.

b) Discovery timeline

In the event that the Court denies the pending Motion to Dismiss or if the Court orders Simonian to file an Amended Complaint, the parties propose the following discovery schedule:

Event	Simonian Proposal	Astellas Proposal
Meet and Confer on E-discovery or other open Rule 26(f) issues	14 days after answer	Agreed
Submit Rule 26(f) Report	14 days after Rule 26(f) conference	Agreed
Exchange Initial Disclosures (Rule 26(a)(1))	21 days after answer	Agreed
Fact Discovery Opens	21 days after answer	Agreed
Fact Discovery Closes	Six months after discovery opens	Agreed – with exception that discovery on financial issues related to size of “penalty” should be bifurcated from liability phase
Simonian Serves Expert Reports	28 days after close of fact discovery ²	Agreed – with exception that expert reports on “penalty” should be bifurcated from liability phase ³
Astellas Serves Rebuttal Reports	28 days after Simonian	Agreed – with exception that

² Simonian has not yet determined whether he will use expert testimony on the liability issue in the case.

³ Given the nature of the issues in the case, Astellas believes that experts on liability, will neither be needed nor proper.

Event	Simonian Proposal	Astellas Proposal
	serves reports	expert reports on “penalty” should be bifurcated from liability phase
Complete Expert Depositions	None	28 days after Astellas serves rebuttal reports
Deadline for Dispositive Motions	28 Days after Astellas serves rebuttal reports	Agreed
Discovery Reopens for Issues Relating to Proper Penalty	Opposes Bifurcation	In the event Astellas’s motion for summary judgment is denied, upon issuance of said order
Discovery Closes on Issues Relating to Proper Penalty	Opposes Bifurcation	56 days (8 weeks) after discovery reopens
Simonian Serves Penalty Expert Reports	Opposes Bifurcation	28 days after penalty discovery closes
Astellas Serves Penalty Rebuttal Reports	Opposes Bifurcation	28 days after Simonian serves reports
Complete Expert Depositions	None/Opposes Bifurcation	28 days after Astellas serves rebuttal reports
Final Pre-trial Order, Motions in Limine, Trial	Subject to the Court’s trial calendar	Agreed

4. Trial

A jury trial has been requested by Simonian (Dkt. #1); Astellas anticipates filing a jury demand with any required Answer. The parties anticipate that it would take approximately 3 days to complete trial.

5. Consent to Proceed before a Magistrate Judge

The parties have not agreed to proceed before a magistrate judge.

6. Status of Settlement Discussions

No settlement discussions have occurred.

Dated: September 23, 2010

Respectfully submitted:

For the Relator Thomas A. Simonian:

For the Defendant Astellas Pharma US, Inc.:

By: s/ Martin Goering

By: /s/ Jaclyne D. Wallace

Attorneys for Relator

Attorneys for Defendants

Joseph M. Vanek
David P. Germaine
John P. Bjork
VANEK, VICKERS & MASINI, P.C.
111 S. Wacker Drive, Suite 4050
Chicago, Illinois 60606
(312) 224-1500

Gregory S. Norrod
Jaclyne D. Wallace
FOLEY & LARDNER, LLP
321 North Clark Street, Suite 2800
Chicago, Illinois 60654
(312) 832-4500

Bruce S. Sperling
Robert D. Cheifetz
SPERLING & SLATER, P.C.
55 West Monroe Street, Suite 3200
Chicago, Illinois 60603
(312) 641-3200

Martin Goering
Jessica Rissman
EUGENE M. CUMMINGS, P.C.
One North Wacker Drive, Suite 4130
Chicago, Illinois 60606
(312) 984-0144

CERTIFICATE OF SERVICE

The undersigned attorney hereby certifies that on September 23, 2010, a true and correct copy of the parties' **JOINT STATUS REPORT** was filed electronically with the Clerk of the Court and was served via the Court's CM/ECF System which will automatically provide electronic notice upon all counsel of record.

/s/ Jaclyne D. Wallace

Jaclyne D. Wallace
Attorney for Defendant